

### **REMARKS**

Claims 1-16 were pending in the present application with claims 2, 3, and 7-12 having been withdrawn from further consideration. By the present communication, no claims have been added, claim 5 has been canceled without prejudice, and claim 1 has been amended. Support for the amended claim language may be found throughout the specification and claims as filed. Accordingly, upon entry of the present communication, claims 1, 4, 6, and 13-16 will be under consideration.

### **Objections to the Specification**

The Office Action alleges that the priority information at page 1 of the application is incorrect. Without acquiescing the reasoning of the Action and in order further prosecution, Applicant has amended the priority information of the specification. Withdrawal of the objection is respectfully requested.

### **Rejections under 35 U.S.C. §112, Second Paragraph**

Applicant respectfully traverses the rejection of claims 1, 4-6, and 13-16 under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. Applicant has canceled claim 5, rendering the rejection moot as to that claim.

The Office Action alleges that reference to a “functional variant” in claim 1 is “not understood because the specification does not provide a definition for this term such that one skilled in the art could know the meets and bounds of this variant.” (Office Action, page 2). Without acquiescing to the reasoning offered by the Office, and in order to expedite prosecution of the instant application, Applicant has amended claim 1 to remove the term. Accordingly withdrawal of the rejection is respectfully requested.

**Rejections under 35 U.S.C. §102**

Applicants respectfully traverse the rejection of claims 1, 4, and 13-16 under 35 U.S.C. §102(b) as allegedly being anticipated by Schutze-Redelmeir, *et al.* (*J. Immunol.* 1996 157:650-655; hereinafter "Schutze-Redelmeir"). To anticipate, a single reference must inherently or expressly teach each and every element of claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). M.P.E.P. § 2131

The Office Action alleges that Schutze-Redelmeir discloses fusion proteins comprising the homeodomain of antennapedia and amino acids 170-179 of JLA-Cw3 CTL epitope or amino acids 147-156 of influenza nucleoprotein peptide. Without acquiescing to the reasoning of the Action and in order to further prosecution of the instant application, Applicant has amended claim 1 to require that the second region of the conjugate comprises a protein of at least 100 amino acids. Support for the amended claim language may be found at, for example, paragraph [0063] and claim 5 of the published specification (U.S. Pub. No. 2008/0317773). Therefore, since Schutze-Redelmeir fails to disclose a conjugate comprising the homeodomain of antennapedia and a second region comprising a protein of at least 100 amino acids, Applicant respectfully submits that Schutze-Redelmeir fails to anticipate the amended claims. Withdrawal of the rejection is respectfully requested.

Applicants respectfully traverse the rejection of claims 1, 4-6, 15 and 16 under 35 U.S.C. §102(b) as allegedly being anticipated by Saffman, *et al.* (*Proc. Natl. Acad. Sci.* 2004 91:7420-7424; hereinafter "Saffman"). Applicant has canceled claim 5, rendering the rejection moot as to that claim.

The Office Action alleges that Saffman discloses fusion proteins comprising different regulatory elements of 3 different homeotic proteins. Among the disclosed fusion proteins are UAA, which comprises the homeodomain and C-tail of antennapedia and the N-terminal of ultrabithorax, which is alleged to be of at least 225 amino acids.

Applicant respectfully submits that the fusions created by Saffman were used to “investigate the roles of [the domains of the homeoproteins] in regulation. (Saffman, p. 422, col. 2). More specifically, chimeric homeoproteins with parts of UBX replaced by ANTP, as shown in Figure 3 of Saffman, were assayed for their ability to regulate the ANTP promoter, P1. Reference 14 of Saffman (Transcriptional activation and repression by Ultrabithorax proteins in cultured *Drosophila* cells, *Cell*, Volume 57, Pages 1031-1043), describes the genes used by Saffman. As indicated in the Office Action, Saffman produced fusions of homeotic proteins, which are related but distinct developmental regulators that specify the differences in the body segments of *Drosophila* (Office Action, page 4, citing to Saffman). Thus, the fusions proteins of Saffman were constructed for the purpose of studying homeotic regulatory specificities for a particular promoter, and were generated using the promoter sequences of *Antp* and not just the 180bp as used in the instant invention. As such, Applicant submits that the protein fragments of Saffman are all “naturally associated.”

In contrast to Saffman, the claimed invention requires that the second region is “not naturally associated with the first region.” Applicant submits that because the second region of the claimed conjugate is not naturally associated with the first region (*i.e.*, the homeodomain of *antennapedia*), the first region has no functional (*e.g.*, regulatory) effect on the second region. In other words, the first region is used to “translocate[d] a protein of at least 100 amino acids across the cell membrane.” (see, *e.g.*, paragraphs [0026] and [0115] of the published specification).

Therefore, since Saffman is absolutely silent with regard to generating a conjugate wherein the second region is “not naturally associated with the first region” and therefore not regulated by ANTP, Applicant respectfully submits that Saffman fails to anticipate the claims. Accordingly, withdrawal of the rejection is respectfully requested.

In re Application of:  
Andrea Crisanti.  
Application No.: 10/789,403  
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PATENT  
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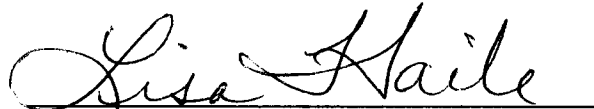
**Conclusion**

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge the amount of \$555.00 as payment for the Three-Month Extension of Time fee to Deposit Account No. 07-1896. No other fees are believed to be due with the filing of this paper. However, if any fee is required, authorization is hereby given to charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 07-1896, referencing the above-identified attorney docket number.

Respectfully submitted,

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